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EXAMINER

BUI, VY Q

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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 10/054,745  
Filing Date: January 22, 2002  
Appellant(s): DONOHOE ET AL.

**MAILED**  
**FEB 05 2007**  
**Group 3700**

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Brian A. Schar  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed 11/07/2006 appealing from the Office action (Final Office Action) mailed 5/18/2006.

**(1) Real Party in Interest**

A statement identifying by name the real party in interest is contained in the brief.

**(2) Related Appeals and Interferences**

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

**(3) Status of Claims**

The statement of the status of claims contained in the brief is correct.

**(4) Status of Amendments After Final**

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

**(5) Summary of Claimed Subject Matter**

The summary of claimed subject matter contained in the brief is correct.

**(6) Grounds of Rejection to be Reviewed on Appeal**

The appellant's statement of the grounds of rejection to be reviewed on appeal is substantially correct. The changes are as follows:

**A. Claims 1-15:**

Independent claim 1 stands finally rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 3,825,362 to Hougen ("Hougen"). Dependent claims 2-6

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(incorrectly listed as claims 5-6) and 8-14 also stand rejected under Hougen. Independent claim 1 also stands finally rejected under 35 U.S.C. § 102(b) as being anticipated by the St. Jude Medical Instructions for Use."3 Dependent claims 7 and 15 also stand finally rejected under that reference.

**B. Claims 17-51:**

Independent claim 17 and dependent claims 18-31, 33-39 and 51 stand finally rejected under 35 U.S.C. § 102(b) as being anticipated by Hougen.

**(7) Claims Appendix**

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(8) Evidence Relied Upon**

3,825,362

Hougen

7-1974

"St. Jude Medical, Instruction for use" (published about August, 2000 as disclosed in applicant's "Remarks", paper 02/16/2006, last paragraph of page numbered 11 to first paragraph of page 12 ).

**(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-6, 8-14, 17-31, 33-39 and 51 are rejected under 35 U.S.C. 102(b) as being anticipated by Hougen-3,825,362.

Hougen-'362 (Figs. 1-15) discloses curved and inwardly beveled rotatable cutter/blade 14, piercing member/auger/spike 42 coaxially disposed within cutter/blade 14, flexible and retractable actuator/coil spring 70, centering flange having threads/grooves adjacent shoulder 50 (Fig. 2), casing 24 defining a contact structure to slidingly receive the auger and cutter assembly, knob 38, seal housing 28 having tip/guide 30 and bushing 32 following guide 30 (Fig. 1-2) as recited by the claims.

2. Claims 1, 7 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by "St. Jude Medical, Instruction for use" (published about August, 2000 as disclosed by the applicant).

Figs. 14 and 15 of "St. Jude Medical, Instruction for use" shows a device as recited in the claims including a cutter beveled outward and a needle/barb/spike having a width at the proximal end greater than the width of the needle shaft.

***Allowable Subject Matter***

Claims 32, 34, 40-50 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

**(10) Response to Argument**

1. Claims 1-15: as to independent claim 1, the Applicants argue that:

a. "As set forth in the specification, the phrase "translate together" means that the piercing member and the cutter are "fixed axially, but independent rotationally.", and "That is, the auger and the cutter are fixed [to one another] with respect to translation, but not with respect to rotation." , and "... Thus, the piercing member and the cutter are fixed to one another with respect to translation "to penetrate the wall of the vessel.", and

"Hougen-'362 neither expressly nor inherently describes the claimed piercing member and cutter configured to translate together to penetrate the wall of a vessel", and

"cutter and piercing member of Hougen...are fixed together as one-unit device [sic]" is simply wrong. Because Hougen discloses only a pilot pin 42 and cutter 14 that move in opposite directions to cut a hole in a workpiece, Hougen does not and cannot disclose a piercing member and a cutter that translate together to penetrate the wall of a vessel, and Hougen neither expressly nor inherently describes each and every element claimed in claim 1" (Arguments, 3Appeal Brief, paper 11/07/2006).

b. "Further, claim 1 is directed to a surgical tool, and requires that "said piercing member and said cutter are configured to translate together to penetrate the wall of the vessel" that is identified in the preamble. However, the device of Hougen is a "machine tool" that is used to make holes in "conduit, a vehicle frame or body member, etc." (Hougen; col. 1, lines 63-65; col. 2, lines 50-51). As a result, Hougen discloses nothing about a piercing member and cutter that are configured to translate together to penetrate the wall of a vessel."

c. "With regard to dependent claim 9, the claim requires that "said piercing member holds the tissue removed from the wall of the vessel."Is However, the "primary object" of the Hougen is "ejecting the round slug formed by the cutter from within the cup portion of the cutter

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upon completion of the hole cutting operation."19 "Ejecting" is the opposite of the claimed "holding."

d. "With regard to claim 10, the claim term "hemostatic" is related to the flow of blood. Blood, much less blood flow, is not expressly or inherently described in Hougen. Thus, Hougen does not and cannot disclose a cutter that is substantially hemostatic.

In response, the Examiner would like to bring the following to the Applicants attention:

a. the specification as disclosed does not explicitly define the meaning of the phrase "translate together", but only is referred to as one way to understand the terms "translate together", and the features (piercing member and cutter being axially fixed and rotationally independent), as mentioned in the above argument by the Applicants are not explicitly claimed in claim 1.

Further, Hougen-'362 device/assembly as shown in Fig. 2., for example, having cutter 14 and auger/spike/piercing member 42 configured to translate together to penetrate the wall 12 because a user of the Hougen device/assembly will move/translate the device/assembly including cutter 14 and auger/spike/piercing member 42 in a direction substantially perpendicular to the surface of wall 12 to cut the wall. Notice that during a translation movement of Hougen device before contacting wall 12, cutter 12 and auger/spike/piercing member 42 are axially fixed one to each other because there is substantially no relative motion between cutter 14 and auger/spike/piercing member 42.

b. Hougen may disclose a different use from that of the device of the present invention. However, the Hougen device is capable of cutting a wall of a vessel as recited in the claim.

As to the reference of "St Jude Medical instruction for Use", a similar rationale is applicable to the Applicants' arguments.

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c. As to claim 9, see Fig. 8, where auger/spike/piercing member 100 holds the wall portion 96 removed from the wall 94.

d. As to claim 10, the cutter can be considered as a cap or a plug being substantially hemostatic.

2. Claims 17-31, 33-39 and 51:

As to independent claim 17, the same reasoning for rejection is applicable.

As to claim 21, cutter 14 has more than one axis.

As to claims 23-24, Hougen's Fig. 8-9 show flange 98 having a through slot to receive piercing member 104 and groove 86.

As to claim 25, casing 24 of Hougen device shown in Fig. 4 does not contact wall 12. However, the claim does not require casing 24 to contact wall 12 (Hougen's Fig. 4).

As to claim 30, seal housing/U-shaped yoke 28 having introducing tips defines/configures an opening big enough to allow the auger and cutter to slide through (Hougen's Fig. 4).

As to claim 33, the bottom of U-shaped yoke 28 can be used as one guide.

As to claim 38, Hougen (Fig. 2; col. 2, lines 56-60) discloses spindle 40 of a machine such as a press drill to provide impulse source configured to rotate and translate the auger 42 and cutter 14.

**(11) Related Proceeding(s) Appendix**

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.



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For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,



01/18/2007

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